





UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER OF PATENTS AND TRADEMARKS
Washington DC 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---------------------------------|--------------------------------|----------------------|------------------------|-----------------|
| 09:730,174 | 12/05/2000 | Richard J. Zahradnik | IMUNE-001A | 8045 |
| 7663 | 7590 07.02-2002 | | | |
| STETINA BRUNDA GARRED & BRUCKER | | | EXAMINER | |
| | RISE, SUITE 250 O, CA 92656 | | HUYNH, PHUONG N | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | \overline{a} |
| | | | DATE MAILED 07 02 2002 | 7 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| , | | Application No. | Applicant(s) | | | | | |
|--|--|--|---|--------------|--|--|--|--|
| | | 09/730,174 | ZAHRADNIK ET AL | | | | | |
| Office Action Sun | nmary | Examiner | Art Unit | | | | | |
| | | " Neon" Phuong Huynh | 1644 | | | | | |
| | is communication app | ears on the cover sheet wi | ith the correspondence add | ress | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>One</u> MONTH(S) FROM | | | | | | | | |
| A SHORTENED STATUTORY THE MAILING DATE OF THIS - Extensions of time may be available unde after SIX (6) MONTHS from the mailing de - If the period for reply specified above, tl - Failure to reply within the set or extended - Any reply received by the Office later than earned patent term adjustment. See 37 C Status | COMMUNICATION. r the provisions of 37 CFR 1.13 te of this communication. ss than thirty (30) days, a reply maximum statutory period w period for reply will, by statute, three months after the mailing | 6(a). In no event, however, may a r within the statutory minimum of thin ill apply and will expire SIX (6) MON cause the application to become AB | eply be timely filed by (30) days will be considered timely. ITHS from the mailing date of this com SANDONED (35 U.S.C.§ 133). | nmunication. | | | | |
| 1) Responsive to communi | cation(s) filed on | _· | | | | | | |
| 2a) This action is FINAL . | 2b)∐ Thi | s action is non-final. | | | | | | |
| 3) Since this application is | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | th the practice under <i>E</i> | ex parte Quayle, 1955 C.I | D. 11, 433 O.G. 213. | | | | | |
| 4) | ling in the application. | | | | | | | |
| 4a) Of the above claim(s) | is/are withdraw | n from consideration. | | | | | | |
| 5) Claim(s) is/are allo | Claim(s) is/are allowed. | | | | | | | |
| 6) Claim(s) is/are reje | 3) Claim(s) is/are rejected. | | | | | | | |
| 7) Claim(s) is/are obj | Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) 1-24 are subject to restriction and/or election requirement. | | | | | | | | |
| Application Papers | | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | | |
| 2. Certified copies of | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | | |
| a) The translation of the foreign language provisional application has been received. | | | | | | | | |
| 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | | |
| Attachment(s) | | 4) Interview | Summary (PTO-413) Paper No(s) | 1 | | | | |
| Notice of References Cited (PTO-892 Notice of Draftsperson's Patent Drawi Information Disclosure Statement(s) (| ng Review (PTO-948) | 5) Notice of I | nformal Patent Application (PTO- x Cover Sheet | | | | | |

Application/Control Number: 09/730,174

Art Unit: 1644

DETAILED ACTION

- 1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
- 2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3. Claims 1-24 are pending.

Election/Restrictions

- 4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Claim 1, drawn to an antigenic peptide for inducing the formation of antibodies comprising a formula SEQ ID NO: 1 and SEQ ID NO: 2, classified in Class 530, subclass 327.
 - II. Claim 2, drawn to an antigenic peptide for inducing the formation of antibodies comprising a formula SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5 and SEQ ID NO: 6, classified in Class 530, subclass 327
 - III. Claim 3, drawn to an antigenic peptide for inducing the formation of antibodies comprising a formula SEQ ID NO: 7 and SEQ ID NO: 8, classified in Class 530, subclass 327.
 - Claim 4, drawn to an antigenic peptide for inducing the formation of antibodies comprising a formula SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11 and SEQ ID NO: 12, classified in Class 530, subclass 326.

Application/Control Number: 09/730,174

Art Unit: 1644

V. Claim 5, 7-11, 14-18, and 24 drawn to a method for producing antibodies useful in the determination of PTH levels in a biological sample wherein said antibodies is capable of binding to a second peptide antigen having a formula SEQ ID NO: 1 and SEQ ID NO: 2, and a kit comprising said antibodies classified in Class 435, subclass 70.21, 810, and Class 530, subclass 387.1.

VI Claims 5-12, 14-17, 19, 22 and 24, drawn to a method for producing antibodies useful in the determination of PTH levels in a biological sample wherein said antibodies is capable of binding to a second peptide antigen having a formula SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5 and SEQ ID NO: 6, and a kit comprising said antibodies classified in Class 435, subclass 70.21, 810, and Class 530, subclass 387.1.

VII. Claims 5, 7-11, 14-17, 20, and 24, drawn to a method for producing antibodies useful in the determination of PTH levels in a biological sample wherein said antibodies is capable of binding to a second peptide antigen having a formula SEQ ID NO: 7, and SEQ ID NO: 8, and a kit comprising said antibodies classified in Class 435, subclass 70.21 and 810, and Class 530, subclass 387.1.

VIII. Claim 5, 7-11, 13, 14-17, 21 and 23-24, drawn to a method for producing antibodies useful in the determination of PTH levels in a biological sample wherein said antibodies is capable of binding to a second peptide antigen having a formula SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11 and SEQ ID NO: 12, classified in Class 435, subclass 70.21, 810, and Class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation. different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the peptides as claimed differ with respect to structure and physiochemical properties. Therefore, they are patentably distinct.

Inventions of Groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of making antibodies that bind to the distinct peptides which differ with respect to their binding specificity. Therefore, they are patentably distinct.

Application/Control Number: 09/730,174

Art Unit: 1644

Inventions of Groups (I-IV) and Groups (V-VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptides as claimed can be used in materially different process such as screening assays. Therefore, they are patentably distinct.

- 5. Because these inventions are distinct for the reasons given above and the searches are not coextensive, restriction for examination purposes as indicated is proper.
- 6. Due to the complexity of the claimed invention an oral restriction was not made.
- 7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
- 9. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette. 1096 OG 30 (November 15, 1989). The CMI Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.

Patent Examiner

July 1, 2002

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600